products for which the information is being accumulated and preserved.

(b) Every dealer or distributor who elects to hold and preserve information required pursuant to §1002.40 shall preserve the information for a period of 5 years from the date of the sale, award, or lease of the product, or until the dealer or distributor discontinues dealing in, or distributing the product, whichever is sooner. If the dealer or distributor discontinues dealing in, or distributing the product, such information as obtained pursuant to §1002.40 shall be furnished at that time, or before, to the manufacturer of the product.

[38 FR 28625, Oct. 15, 1973, as amended at 42 FR 18063, Apr. 5, 1977; 53 FR 11254, Apr. 6, 1988]

§1002.42 Confidentiality of records furnished by dealers and distributors.

All information furnished to manufacturers by dealers and distributors pursuant to this part shall be treated by such manufacturers as confidential information which may be used only as necessary to notify persons pursuant to section 359 of the Act.

Subpart F—Exemptions From Records and Reports Requirements

§1002.50 Special exemptions.

(a) Manufacturers of electronic products may submit to the Director a request, together with accompanying justification, for exemption from any requirements listed in table 1 of §1002.1. The request must specify each requirement from which an exemption is requested. In addition to other information that is required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested does not pose a public health risk and meets at least one of the following criteria:

(1) The products cannot emit electronic product radiation in sufficient intensity or of such quality, under any conditions of operation, maintenance, service, or product failure, to be hazardous;

(2) The products are produced in small quantities;

(3) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training.

(4) The products are custom designed and used by trained individuals knowledgeable of the hazards; or

(5) The products are produced in such a way that the requirements are inappropriate or unnecessary.

(b) The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which the Director may possess if the Director determines that such exemption is in keeping with the purposes of the Act.

(c) The Director will provide written notification of the reason for any denial. If the exemption is granted, the Director will provide written notification of:

(1) The electronic product or products for which the exemption has been granted;

(2) The requirements from which the product is exempted; and

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Office of Compliance (HFZ–307), Center for Devices and Radiological Health, 2098 Gaither Rd., Rockville, MD 20850.

(d) The Director may, on the Director's own motion, exempt certain classes of products from the reporting requirements listed in table 1 of §1002.1, provided that the Director finds that such exemption is in keeping with the purposes of the act.

(e) Manufacturers of products for which there is no applicable performance standard under parts 1020 through 1050 of this chapter and for which an investigational device exemption has been approved under §812.30 of this chapter or for which a premarket approval application has been approved in